PATENT COOPERATION TREA

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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GRANDE BRETAGNE

File 96.79544/002
- 2 FEB 2005
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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	01.02.2005
Applicant's or agent's file reference: 96.79544/002	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 03/04751	04.11.2003	04.11.2002

Applicant: CAMBRIDGE CONSULTANTS LIMITED ET AL.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

European Patent Office - P.B. 5818 Patentlaan 2
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 96.79544/002	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/04751	International filing date *(day/month/year)* 04.11.2003	Priority date *(day/month/year)* 04.11.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant CAMBRIDGE CONSULTANTS LIMITED ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02.06.2004	01.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04751

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-28	as originally filed

Claims, Numbers

9-14	as originally filed
15-27	received on 20.03.2004 with letter of 20.03.2004
1-8, 28-35	received on 29.10.2004 with letter of 29.10.2004

Drawings, Sheets

1/10-10/10	received on 20.03.2004 with letter of 20.03.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT International application No. PCT/GB 03/04751

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 9-34

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 9-34

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04751

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-8, 35 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-8, 35
	No:	Claims	-
Inventive step (IS)	Yes:	Claims	1-8, 35
	No:	Claims	-
Industrial applicability (IA)	Yes:	Claims	1-8, 35
	No:	Claims	-

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/GB 03/04751

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 9-34 were not searched in view of Rule 13.1 PCT (see Box IV below) and therefore no substantive examination can be performed on these claims.

Re Item IV

Lack of unity of invention

This International Examining Authority found multiple (groups of) inventions in this international application, as follows:

Group 1: Claims 1 - 8, 35

A metered dose inhaler comprising:

A) means for receiving a medicament canister

B) breath-actuated latch mechanism

Group 2: Claims 9 - 11, 12 - 16

An inhaler comprising:

C) a mouthpiece

D) a mouthpiece cover, closing the air inlet

Group 3: Claims 17 - 20

A metered dose inhaler comprising:

E) a dose counter, with helically toothed track

Group 4: Claims 21 - 25, 27 - 28, 29 - 30, 32

A pressurised canister for dispensing a metered dose, comprising:

F) a valve with a sliding, biased nozzle

G) a metering chamber

Group 5: Claim 26

An inhaler device, comprising:

A) means for receiving a medicament carrier

Group 6. Claims 31, 33, 34

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET International application No. PCT/GB 03/04751

A valve, comprising:
F) a resiliently biased nozzle

In order that an International Application may contain more than one invention, the inventions defined in the application must form "a group", namely they should be so linked, as to form a single general inventive concept (see Rule 13.1 PCT). This inventive concept finds expression in the independent claims according to the different inventions in terms of the same or corresponding special technical features. The definition "special technical features" refers to the features which, in the independent claims, involve an inventive step over the prior art.

In the present case the common or corresponding features of independent claims 1, 9, 12, 17, 26, and 35 are a generic features of a metered dose inhaler: means for receiving a medicament canister A), mouthpiece B), which are disclosed in combination in the documents cited in the search report and are therefore not only not involving an inventive concept over the prior art, but are not even new.

As this inhaler is defined only as being suitable for receiving a medicament carrier, it has no technical features in common with the canister or the valve as disclosed in the remaining independent claims (claims 21, 27, 29, 31, 33, and 34).

The common or corresponding feature of claims 21, 27, 29, 31, 33, and 34 is valve F). Such a valve is likewise disclosed in the documents of the search report and is therefore also not only not involving an inventive step, but is not even new.

The remaining features of the independent claims, namely breath actuated latch B), mouthpiece cover D), dose counter E), valve/nozzle F) and metering chamber G), are different and have different purposes.

Therefore the application is considered to encompass six different, separate inventions, contrary to the requirements of Rule 13.1 PCT.

No additional fees were paid. Therefore, examination is limited to the claims of group 1: claims 1-8 and 35.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial

applicability; citations and explanations supporting such statement

The document US-A-5408994 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

> a metered dose inhaler comprising means for receiving a pressurised medicament canister; and a breath actuated latch mechanism arranged in use to latch a spring in line with said canister, said latch to be released in response to inhalation through the inhaler by the user, thereby depressing said canister to dispense a metered dose.

The subject-matter of claim 1 differs from this known inhaler in that the canister itself is latched in a depressed condition. The medicament is to be dispensed when the canister is released from its depressed state.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as minimising the space required for the actuation of the inhaler.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons: The canister to be used in the device releases its dose exactly opposite to conventional medicament canisters. A simple latch mechanism anticipating such a canister is not disclosed in any of the prior art documents as currently available.

Claim 35 differs from claim 1 in that the inhaler is not limited to being a metered dose inhaler. As a metered dose is usually metered by the canister, the features of claim 35 is considered to correspond to claim 1. Claim 35 therefore involves an inventive step (Article 33(3) PCT) for the same reasons as cited above.

Claims 2 to 8 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.